Complete Summary

GUIDELINE TITLE

Donovanosis (granuloma inguinale). In: Sexually transmitted infections: UK national screening and testing guidelines.

BIBLIOGRAPHIC SOURCE(S)

Richens J. Donovanosis (granuloma inguinale). In: Ross J, Ison C, Carder C, Lewis D, Mercey D, Young H. Sexually transmitted infections: UK national screening and testing guidelines. London (UK): British Association for Sexual Health and HIV (BASHH); 2006 Aug. p. 52-6. [13 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Donovanosis (granuloma inguinale)

GUIDELINE CATEGORY

Diagnosis
Screening

CLINICAL SPECIALTY

Family Practice
Infectious Diseases

Internal Medicine
Obstetrics and Gynecology
Urology

INTENDED USERS

Advanced Practice Nurses
Clinical Laboratory Personnel
Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

- To provide advice on what tests for donovanosis are most appropriate in a United Kingdom (UK) genitourinary (GU) clinic setting (excluding human immunodeficiency virus [HIV]-infected patients)
- To provide a basis for audit
- To support clinics when bidding for additional resources to meet national standards

TARGET POPULATION

Individuals in the United Kingdom presenting with unusual forms of ulceration where diagnoses other than donovanosis have been ruled out and a suggestive travel history is obtained

INTERVENTIONS AND PRACTICES CONSIDERED

1. Stained (Giemsa, Wright, Leishman, Rapi-diff) tissue smear
2. Punch or snip biopsy
3. Bacterial culture (not available in the United Kingdom [UK]):
    - Medium (peripheral blood mononuclear cells, Hep-2 cells)
    - Removal of contaminants with vancomycin or metronidazole pretreatment
4. Polymerase chain reaction (PCR) (not available in the UK)
5. Clinical assessment to assess cure

MAJOR OUTCOMES CONSIDERED

Reliability of test methods

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Search for Evidence

The Medline database and Cochrane library were searched up to July 2002, using the MESH heading granuloma inguinale and free text searches using "donovanosis", "granuloma inguinale", "calymmatobacterium" and "klebsiella granulomatis". All published papers dealing with diagnosis of donovanosis were obtained and read for a review published in 1991. Other sources of information used were the Sexually Transmitted Infections (STI) Guidelines for the United Kingdom (UK), Europe, United States of America (USA) (Centers for Disease Control and Prevention [CDC]) and World Health Organization (WHO), "Donovanosis control or eradication? A situation review of donovanosis in Aboriginal and Torres Strait Islander populations in Australia" by Penny Miller, published by Office for Aboriginal and Torres Strait Islander Health, GPO 9848 (MDP 17), Canberra ACT 2601 and recent articles in press or in preparation sent to the author for comment or peer review.

Criteria for Including/Excluding Evidence

All articles retrieved by the above search strategy that deal with diagnosis have been consulted as the total number is relatively small and manageable. No systematic reviews have been published in this area.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Ia: Evidence obtained from meta-analysis of randomised controlled trials

Ib: Evidence obtained from at least one randomised controlled trial

IIa: Evidence obtained from at least one well designed controlled study without randomisation

IIb: Evidence obtained from at least one other type of well designed quasi-experimental study

III: Evidence obtained from well designed non-experimental descriptive studies

IV: Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The guidelines have been developed following the methodological framework of the Appraisal of Guidelines Research and Evaluation instrument (AGREE - adapted as described in *Int J STD and AIDS* 2004 15:297-305).

The extent to which the guideline represents the views of intended users has been addressed primarily by the authorship coming from the multidisciplinary membership of the Bacterial Special Interest Group (BSIG). As practising clinicians the authors were able to draw on their experience of applying the tests to symptomatic and asymptomatic patients but it was not feasible to obtain formal input from representative patients.

Research on donovanosis has been conducted by only 2 specialists in the UK (the author, John Richens, and Dr Nigel O'Farrell) who have both agreed to the recommendations in this guideline. Advice has also been obtained from Francis Bowden a leading Australian expert.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grading of Recommendations

A. Evidence at level Ia or Ib
B. Evidence at level IIa, IIb, or III
C. Evidence at level IV

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

After drafting, other health care professionals and professional bodies in genitourinary (GU) medicine were asked to comment, the draft guidelines posted on the British Association for Sexual Health and HIV (BASHH) website for 3 months, and all comments reviewed before final publication.

Prior to submission this guideline was circulated to two leading international experts with knowledge of donovanosis. Their comments were noted and incorporated into the current document.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the level of evidence (**I-IV**) and grade of recommendation (**A-C**) are provided at the end of the "Major Recommendations" field.

Screening is recommended only for patients presenting with unusual forms of ulceration where other diagnoses have been ruled out and a suggestive travel history is obtained. Screening of asymptomatic patients attending United Kingdom (UK) genitourinary (GU) clinics is not indicated. Contacts of known cases should undergo careful examination.

Recommended Tests for Suspected Clinical Cases of Donovanosis

Examination of Stained Smears for Donovan Bodies (Evidence Level IV, Grade of Recommendation C)

This method was that originally described by Donovan in 1905 and has been the most widely used since then. Donovan bodies show up well with Giemsa, Wright's and Leishman stains. Rapi-diff is a useful quick version of the Giemsa stain. This approach to diagnosis has been recommended consistently as a simple and reliable method.

Specimen collection: surface debris from purulent ulcers should be removed gently with a cotton swab, after this the lesion may be pressed directly on to a glass slide, or material collected by rolling a swab over the lesion and then on to a slide. The slide should be air-dried and either stained immediately or, where this is not possibly, fixed in 95% ethanol for 5 minutes and stained later. This approach to diagnosis works well in patients whose lesions have plentiful Donovan bodies. Additional methods listed below are more suitable for cases with low numbers of Donovan bodies.

Biopsy (Evidence Level IV, Grade of Recommendation C)

Biopsy may be considered for smear negative lesions, large lesions with easily removed friable tissue, any lesion where malignancy is suspected and less common lesions of the mouth, anus, cervix and uterus. Examination of biopsy material is more time-consuming and may involve greater discomfort for the patient. Good results may be obtained by taking up to three 3 to 5 mm punch or snip biopsies and placing them in 10% formalin/saline solution. Smears for more rapid diagnosis may be made by smearing the inferior surface of one of the biopsy specimens on to a glass slide, avoiding re-spreading of any area and stopping when the specimen becomes dry. Biopsy tissue may be examined with the stains recommended for smears and also with silver stains or slow Giemsa.

Culture (not currently available in UK) (Evidence Level IIa, Grade of Recommendation B)

Successful culture has been reported in human peripheral blood mononuclear cells and in Hep-2 cells. So far these techniques have only been successfully utilized by two research laboratories outside the UK (Darwin and Durban). Pre-treatment of specimens with antibiotics such as vancomycin and metronidazole is necessary to remove contaminants.

PCR (polymerase chain reaction) (not currently available in the UK) (Evidence Level IIa, Grade of Recommendation B)

A PCR test has been developed in Australia and is used on a small scale in the Australian eradication programme. Testing facilities are located in Queensland and Perth.

Recommended Sites for Testing

- Base or edge of ulcerated lesions.
- Regional lymph nodes if enlarged or ulcerated especially if ulcer gives negative results.

Factors Which Alter Tests Recommended or Sites Tested

Culture and PCR only available in special centres. Use of biopsy depends whether smear diagnosis is achievable and whether biopsy is acceptable to the patient. Sites tested depend on clinical presentation.

Risk Groups

- Gay men (no alteration to standard recommendation)
- Sex workers (no alteration to standard recommendation)
- Young patients (no alteration to standard recommendation)

Other

- Pregnant women (no alteration to standard recommendation)
- Women with a history of hysterectomy (no alteration to standard recommendation)

- Patients who are known contacts of the infection (no alteration to standard recommendation)

Recommendation for Frequency of Repeat Testing in an Asymptomatic Patient

- Not applicable

Recommendation for Test of Cure

- Clinical assessment without sampling is sufficient.

Definitions:

Levels of Evidence

Ia: Evidence obtained from meta-analysis of randomised controlled trials

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III: Evidence obtained from well designed non-experimental descriptive studies

IV: Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

Grading of Recommendations

A. Evidence at level Ia or Ib
B. Evidence at level IIa, IIb, or III
C. Evidence at level IV

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for selected recommendations (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate screening of donovanosis

POTENTIAL HARMS

The use of punch biopsies is a standard dermatological procedure for diagnosis of skin diseases and carries the following potential hazards:

- Local bleeding and bruising in the surrounding tissues
- Pain associated with the surgery or the healing process
- Excessive scarring at the surgery site
- Allergic reaction to the numbing medicine or the surgical instruments
- Local infection in the surrounding tissues
- Damage to structures beneath the skin such as an artery or nerve
- Rare, unusual reactions, including possible death following any surgical procedure

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The recommendations given do not call for any changed in the current organization of care.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Richens J. Donovanosis (granuloma inguinale). In: Ross J, Ison C, Carder C, Lewis D, Mercey D, Young H. Sexually transmitted infections: UK national screening and testing guidelines. London (UK): British Association for Sexual Health and HIV (BASHH); 2006 Aug. p. 52-6. [13 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Aug

GUIDELINE DEVELOPER(S)

British Association for Sexual Health and HIV - Medical Specialty Society

SOURCE(S) OF FUNDING

No specific or external funding was sought or provided in the development of this guideline.

GUIDELINE COMMITTEE

Screening Guidelines Steering Committee
Clinical Effectiveness Group (CEG)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Author: John Richens, Department of Sexually Transmitted Diseases, University College London

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Potential conflicts of interest: None

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from British Association for Sexual Health and HIV Web Site.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Specifications for the development of UK guidelines on the management of sexually transmitted infections (STIs) and closely related conditions 2005. London (UK): British Association of Sexual Health and HIV (BASHH); 2005. 14 p. Electronic copies: Available in Portable Document Format (PDF) from the British Association for Sexual Health and HIV Web site.

Additionally, auditable outcome measures can be found in the original guideline document.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on June 24, 2008. The information was verified by the guideline developer on October 20, 2008.

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